

**PACKAGE LEAFLET: INFORMATION FOR THE USER****RHINOHELP 5mg film-coated tablets**  
desloratadine

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

- 1 What **RHINOHELP**<sup>®</sup> is and what is used for
- 2 What you need to know before you take **RHINOHELP**<sup>®</sup>
- 3 How to take **RHINOHELP**<sup>®</sup>
- 4 Possible side effects
- 5 How to store **RHINOHELP**<sup>®</sup>
- 6 Contents of the pack and other information

**1. WHAT RHINOHELP<sup>®</sup> IS AND WHAT IS USED FOR**

**RHINOHELP**<sup>®</sup> is an anti-allergy medicine that does not make you drowsy. It helps control your allergic reaction and its symptoms.

**RHINOHELP**<sup>®</sup> relieves symptoms associated with allergic rhinitis (inflammation of the nasal passages caused by an allergy, for example, hay fever or allergy to dust mites). These symptoms include sneezing, runny or itchy nose, itchy palate, and itchy, red or watery eyes.

**RHINOHELP**<sup>®</sup> is also used to relieve the symptoms associated with urticaria (a skin condition caused by allergy). These symptoms include itching and hives.

Relief of these symptoms lasts a full day and helps you to resume your normal daily activities and sleep.

**2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RHINOHELP<sup>®</sup>****Do not take RHINOHELP<sup>®</sup>**

- if you are allergic (hypersensitive) to desloratadine, to any of the other ingredients of this medicine or loratadine.

**RHINOHELP**<sup>®</sup> is indicated for adults and adolescents (12 years of age and older)

**Take special care with RHINOHELP®**

- if you have poor kidney function.

If this applies to you, or if you are not sure, please check with your doctor or pharmacist before you take **RHINOHELP®**.

**Other medicines and RHINOHELP®**

There are not known interactions of **RHINOHELP®** with other medicines.

**RHINOHELP® with food and alcohol**

**RHINOHELP®** may be taken with or without food.

**Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, ask your doctor or your pharmacist for advice before you take any medicine.

If you are pregnant or breast-feeding, taking **RHINOHELP®** is not recommended.

**Driving and using machines**

At the recommended dose **RHINOHELP®** is not expected to cause you to be drowsy or less alert. However, very rarely some people experience drowsiness, which may affect the ability to drive or use machines.

**3. HOW TO TAKE RHINOHELP®**

Adults and adolescents (12 years of age and older): take one tablet once daily.

Swallow the tablet whole with water, with or without food.

Regarding the duration of treatment, your doctor will determine the type of allergic rhinitis you are suffering from and will determine for how long you should take **RHINOHELP®**.

If your allergic rhinitis is intermittent (presence of symptoms for less than 4 days per week or for less than 4 weeks), your doctor will recommend you a treatment schedule that will depend on the evaluation of the history of your disease. If your allergic rhinitis is persistent (presence of symptoms for 4 days or more per week and for more than 4 weeks), your doctor may recommend you a longer term treatment.

For urticaria, the duration of treatment may vary from patient to patient and therefore you should follow the instructions of your doctor.

**If you take more RHINOHELP® than you should**

Take **RHINOHELP®** only as it is prescribed for you. No serious problems are expected with accidental overdose. However, if you take more **RHINOHELP®** than you were told to, contact your doctor or pharmacist.

**If you forget to take RHINOHELP®**

If you forget to take your dose on time, take it as soon as possible, then go back to your regular dosing schedule. Do not take a double dose to make up for a forgotten dose.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, **RHINOHELP®** can cause side effects, although not everybody gets them. In adults, side effects were about the same as with placebo tablets. However, fatigue, dry mouth and headache were reported more often than with placebo. In adolescents, headache was the most commonly reported side effect.

During marketing of desloratadine, rare cases have been reported of allergic reactions (difficulty in breathing, wheezing, itching, hives and swelling) and skin rash. Also, very rarely have been reported cases of arrhythmia, increase in heartbeat, stomach ache, nausea (feeling sick), vomiting, upset stomach, diarrhea, dizziness, drowsiness, inability to sleep, muscle pain, hallucinations, seizures, restlessness with increased body movement, liver inflammation and abnormal liver function tests.

In case any side effect becomes serious or if you feel any side effect not mentioned in this leaflet, you should contact your doctor or pharmacist.

**5. HOW TO STORE RHINOHELP®**

Keep this medicine out of the site and reach of children.

Do not store above 30°C.

Do not use **RHINOHELP®** after the expiry date, which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Inform your pharmacist if you notice any change in the appearance of the tablets.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. CONTENTS OF THE PACKAGE AND OTHER INFORMATION****What RHINOHELP® contains**

- The active substance is desloratadine 5mg
- The other ingredients of the tablet are:  
Core: Isomalt, Starch, Pregelatinized Celulose, Microcrystalline, Magnesium Oxide, heavy Hydroxypropylcellulose, Crospovidone, Magnesium Stearate.

Coating: Polyvinyl Alcohol, Titanium Dioxide (E171), Macrogol / PEG 3350 Talc, FD&C Blue #2/Indigo Carmine Aluminum Lake (E132)

**What RHINOHELP<sup>®</sup> looks like and contents of the pack**

**RHINOHELP<sup>®</sup>** 5mg film-coated tablets are packed in blisters in pack of 30 tablets.

**Marketing Authorization Holder:**

TARGET PHARMA

54 Menandrou st. 10431 Athens, Greece

Tel.: +30 210 52 24 830, Fax: +30 210 52 24 838

E-mail [info@targetpharma.gr](mailto:info@targetpharma.gr), [www.targetpharma.gr](http://www.targetpharma.gr)

**Manufacturer:**

SPECIFAR ABEE

1, 28<sup>th</sup> of October st.

12351 Agia Barbara, Athens, Greece

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